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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/601,478 | 06/23/2003 | Thomas J. Boyd | IR 7348-00 | 7241 |
| 7590 | 09/16/2005 | | EXAMINER | |
| Colgate-Palmolive Company 909 River Road P.O. Box 1343 Piscataway, NJ 08855-1343 | | | KRASS, FREDERICK F | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/601,478 | BOYD ET AL. |
| | Examiner Frederick F. Krass | Art Unit 1614 |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>A, B & C</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

Informalities

The following informalities are noted and should be corrected in responding to this Office action:

- 1) Claim 1, the free floating amino group clearly needs to be moved so it is attached to the double bond in the structural formula.
- 2) Claim 4, the phrase "the concentration" at the first line is superfluous since that same concentration is repeated later at the second line of the claim. Accordingly, "the concentration" at the first line should be deleted.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- 1) Claim 1 is incomplete insofar as the variable "n" is not defined.
- 2) Claim 6, there is no antecedent basis in claim 1 for reciting "said polyhydric alcohol".

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-4 and 7 are rejected under 35 USC 102(a) as being anticipated by Beltran et al (WO 03/043593).

The prior art discloses personal care compositions containing up to 1 percent by weight of the hydrochloric salt of ethyl lauroyl arginine ("LAE") as an antimicrobial agent. See the first paragraph of p. 4, and see also working example 4 at p. 12 in which an aqueous oral care composition (liquid dentifrice) comprising a surfactant (sodium lauryl sulfate), a mixed polyhydric alcohol humectant (glycerol and sorbitol) and water is specifically prepared. (No monohydric alcohol is included).

2) Claims 1, 2 and 4 are rejected under 35 USC 102(b) as being anticipated by Ohtsuki et al (USP 5,266,306).

The prior art discloses oral care compositions comprising cetylpyridinium and a long chain acyl basic amino acid ester salt, e.g., a long chain arginine ester salt (col. 2, lines 14-34). See also working example 1 at col. 4, wherein an aqueous toothpaste comprising a surfactant (polyoxyethylene polyoxypropylene glycol), a humectant (glycerin), 0.05 percent lauroyl arginine-pyrrolidone carboxylate, and water is specifically prepared. (No monohydric alcohol is included).

3) Claims 1, 2 and 4-7 are rejected under 35 USC 102(b) as being anticipated by Barton et al (USP 5,695,745).

The prior art discloses aqueous oral care compositions comprising a cocoyl arginine ethyl ester salt ("CAE"). See the passage bridging the bottom of col. 2 to the top of col. 3. Preferred humectants include propylene glycol or mixtures of polyhydric alcohols, e.g., glycerol/sorbitol (see the passage spanning the bottom of col. 3 to the top of col. 4), and preferred surfactants comprise mixtures of nonionic and zwitterionic (= amphoteric) species (see the abstract, and also claim 1, of the patent). See also working example 1 at the top of col. 9, wherein an aqueous mouthwash composition comprising 0.48 percent CAE (a percentage falling squarely within Applicant's preferred range of instant claim 4) is prepared. (No monohydric alcohol is included).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claim 3 is rejected under 35 USC 103(a) as being unpatentable over Ohtsuki et al (USP 5,266,306) in view of Beltran et al (WO 03/043593).

The primary reference discloses oral care compositions comprising cetylpyridinium and a long chain acyl basic amino acid ester, e.g., a long chain arginine ester, including arginine esters having lauroyl, myristyl or stearoyl long-chain substituents (col. 2, lines 24-27). It differs from the instant claim insofar as it does not specifically disclose LAE.

The secondary reference is discussed in subsection "1)" of the "Anticipation" section supra, and teaches that LAE, when used in combination with other conventional antimicrobial agents such as chlorhexidine, hexetidine and cetylpyridinium salts provides synergistic antimicrobial activity, thus permitting use of lower amounts of antimicrobial agent such that side effects normally associated therewith are lessened. See p. 2, lines 11-14 and p. 3, lines 20-27. Accordingly, it would have been obvious to have used LAE as the long chain acyl basic amino acid ester of the primary reference, motivated by the desire to provide optimum antimicrobial activity while lessening side effects as taught by the secondary reference.

2) Claim 3 is rejected is rejected under 35 USC 103(a) as being unpatentable over Barton et al (USP 5,695,745) in view of Beltran et al (WO 03/043593).

The primary reference discloses aqueous oral care compositions comprising a quaternary amine, a specific example being cocoyl arginine ethyl ester ("CAE"). See the passage bridging the bottom of col. 2 to the top of col. 3. It differs from the instant claim insofar as it does not specifically disclose LAE.

The secondary reference is discussed in subsection "1)" of the "Anticipation" section supra, and teaches that LAE, when used in combination with other conventional antimicrobial agents such as chlorhexidine, hexetidine and cetylpyridinium salts provides synergistic antimicrobial activity, thus permitting the use of lower amounts of antimicrobial agent such that side effects normally associated therewith are lessened. See p. 2, lines 11-14 and p. 3, lines 20-27. Accordingly, it would have been obvious to have used LAE as the quaternary amine of the primary reference, motivated by the desire to provide optimum antimicrobial activity while lessening side effects as taught by the secondary reference.

3) Claims 6 and 7 are rejected under 35 USC 103(a) as being unpatentable over Ohtsuki et al (USP 5,266,306) in view of Barton et al (USP 5,695,745).

The primary reference discloses oral care compositions comprising cetylpyridinium and a long chain acyl basic amino acid ester, e.g., a long chain arginine ester. See especially working example 1 at col. 4, wherein an aqueous toothpaste comprising a surfactant (polyoxyethylene polyoxypropylene glycol), a humectant (glycerin), 0.05 percent lauroyl arginine-pyrrolidone carboxylate, and water is specifically prepared. (No monohydric alcohol is included). It differs from the instant claims insofar as propylene glycol (instant claim 6) or mixtures of polyols (instant claim 7) are not specifically disclosed as humectants.

Settled law holds that it is generally obvious to add a known ingredient to a known composition, with the expectation of obtaining no more than the expected function of that ingredient. See In re Kerkhoven, 205 U.S.P.Q. 1069 (CCPA 1980); In re Crockett, 126 USPQ 186, 188 (CCPA 1960); In re Linder, 457 F.2d 506, 507 (CCPA 1972); and In re Dial, 326 F.2d 430, 432 (CCPA 1964).

The secondary reference is discussed in subsection "3)" of the "Anticipation" section supra and teaches that propylene glycol, as well as glycerol/sorbitol mixtures, are known humectants for known aqueous oral care compositions comprising quaternary amines such as cocoyl arginine ethyl ester ("CAE"). See the passage bridging the bottom of col. 2 to the top of col. 3. Accordingly, it would have been obvious to have incorporated a known humectant such as propylene glycol or glycerol/sorbitol into

the primary reference compositions for its art-recognized humectant function as taught by the secondary reference, motivated by the guidance provided by the reasoning of the cited precedent.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

